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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,443	02/17/2004	Steven Scampini	PHUS030073	6171

28159 7590 12/13/2005

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EXAMINER

JAWORSKI, FRANCIS J

ART UNIT PAPER NUMBER

3737

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,443	SCAMPINI ET AL.	
	Examiner	Art Unit	
	Jaworski Francis J.	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2-17-04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: Page 8 case status update (now U.S.6723050), page 9 top provisional serial number is in error (60/430,396)..

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 3, 7 – 8, 11-12, 15 – 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayakawa (US6221016) which teaches structure and method of use for an ultrasound surgical puncture needle guidance system to observe and place a biopsy needle comprising probe 20 including a 2D volume scanning array e.g. 211 of Fig. 18 and attendant discussion rendering equivalent the planar and volumetric scanning techniques of the disclosure (col. 11 lines 12-42 and col. 33 lines 14 – 50 where the overall volume-scanned limits are reduced in obedience to scan buildup times), transmit and receive beamformation portions 100, 201-203, for forming coherent echoes per Figs. 5-6, where the transmit beamformation steering and focusing occurs at a relatively higher uniform beam line density in the scan frame or volume subsector of the vicinity of the needle as depicted per Figs. 7a-7c and attendant col. 25 discussion, and

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volumetric image processing via 300, 500 for display onto 707. Both loading information as to probe length type and transmitting ultrasound Doppler tip interrogation by the body surface array in Hayakawa serve to identify the location of the invasive medical device in the imaged volume, see Col. 28 line 5 – col. 29 line 20 therein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4 – 6, 9 – 10, 17 - 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa as applied to claim 1 above, and further in view of Savord (US5678552) since whereas Hayakawa does not teach line density diminution progression, it would nonetheless have been obvious in view of the latter col. 10

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discussion to apply non-uniform angular spacing for multiline processing with respect to a central investigated region of interest as in the former since this was known to obviate the frame rate problem discussed in col. 33 of the former. The minimum skirt beam density would then be fixed by the overall width of the volumetric scan.

Claims 13 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayakawa as applied to claim 11 above, and further in view of Vilkomerson et al (US4249539) or Martin et al (US5398691) insofar as the aforementioned discussion of Fig. 12 of Hayakawa et al relating to emission of vibration by the internally inserted needle tip would have been understood by the artisan to have been implementable as a 'reversal of parts' using passively received signals onto an omnidirectional sensing stylus or needle tip in light of Vilkomerson et al or by alternative electromagnetic position registry for locating an in-body medical device in view of Martin et al col. 7 top where the position determining signal of field generator 20 is passively received by sensor 56 of esophageal probe 14 in an analogous position-locating step.

Greppi et al (US6951542) is cited as of interest as directed to three-dimensional imaging of an inserted needle instrument probe using alternative volume scanning techniques variously optimized for needle and body visualization.

Zhao et al (US6524247) is cited for suggesting three-dimensional needle tip locating scanning as per angulated beamsteering of Ishrak et al (US6048312) where the needle locating beam set is of lesser density than the imaging line set directed to the same

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area, see col. 1 – 2 bridging, col. 3 lines 40-52 and Figs. 4A vs 4B, and col. 12 lines 24 – 34.

Yamazaki (US6336899) is directed to a navigational protocol for paracentesis needle insertion including positional tracking via needle mounted ultrasonic transducers, see Fig. 8 and the latter part of claim 1 as well as extensive discussions of this feature therein.


Grenon et al (US6544178) Fig. 7 and attendant specification discussion is directed to changing transducer position and gain and scan depth in the vicinity of the object scanned (heart catheter, amniocentesis needle) during 3D volumetric tracking acquisitions.

Kessman et al (US6968224), Steins et al (US6733458), Paltieli et al (US6626832) and Lee et al (US6764449) are all cited as of interest in relation to volumetric ultrasound instrument imaging with positional tracking.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

12-8-05


Francis J. Jaworski
Primary Examiner